K063112

RevLite Q-Switched Laser System 510k Summary

DEC - 1 2006

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Contact:	Donna K. Templeman Regulatory Consultant
Date Summary Prepared:	July 31, 2006
Device Trade Name:	RevLite™ Q-Switched Nd: YAG Laser System
Common Name:	Dermatology Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Classification Code:	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.
Equivalent Device:	Focus Medical NaturaLase 1064 2 Joule Laser System – K# Unknown MedLite C6 Q-Switched Nd: YAG Laser System – K014234
Device Description:	The RevLite System laser unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. Laser energy produced within the device is delivered to the tissue by means of an articulated arm and a specially designed MultiSpot Handpiece or optional Multilite Dye Laser Handpieces. The user activates laser emission by means of a footswitch. The RevLite System incorporates 2 very narrow laser applications designed to apply more energy over a larger

	spot size at the same fluence level, enabling the physician to treat a larger area more rapidly.
Intended Use:	For use in dermatology for the following indications: Treatment of Epidermal Pigmented Lesions, Treatment of Dermal Pigmented Lesions Nevus of Ota, Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis, Laser skin resurfacing procedures for the treatment of acne scars and wrinkles, Tattoo Removal: Dark Ink: (Black & Blue) Light Ink: (Red, Sky Blue, Green), Treatment of Vascular Lesions, Removal or lightening of unwanted hair with or without adjuvant preparation
Comparison:	The RevLite Laser System is comparable to its predicate and parent devices in terms of its indications for use, technical specifications, operating performance features, and general design features.
Nonclinical Performance Data:	None
Clinical Performance Data:	none
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hoya ConBio
% Ms. Donna K. Templeman
Regulatory Consultant
47733 Fremont Boulevard
Fremont, California 94538

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Re: K063112
Trade/Device Name: Revlite Q-Switched Nd: YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 31, 2006
Received: November 2, 2006

Dear Ms. Templeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063112

Device Name: **RevLite Q-Switched Nd: YAG Laser System**

Indications for Use:
The RevLite Q-Switched Nd: YAG Laser System is indicated for Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

Specific Indications:

1064 nm wavelength:

Tattoo Removal: Dark Ink: (Black & Blue)

Nevus of Ota

Removal or lightening of unwanted hair with or without adjuvant preparation.

Skin resurfacing procedures for the treatment of acne scars and wrinkles

532 nm wavelength (nominal delivered energy of 585nm and 650 nm with the Optional Multilite Dye Laser Handpiece):

Tattoo Removal: Light Ink (Red, Sky Blue, Green)

Treatment of Vascular Lesions including, but not limited to:

- port wine birthmarks
- telangiectasias
- spider angioma
- cherry angioma
- spider nevi

Treatment of Pigmented Lesions including, but not limited to:

- cafe-au-lait birthmarks
- solar lentiginos
- senile lentiginos
- Becker's nevi
- Freckles

- Nevus spilus

Skin resurfacing procedures for the treatment of acne scars and wrinkles

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063112